09/820198

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

icant:

Jackie R. Bickenbach et al.

Examiner:

Leon B. Lankford, Jr.

al No.:

09/820198

Group Art Unit:

1651

March 28, 2001

Docket:

875.029US1

Title:

METHODS TO PREPARE AND USE EPIDERMAL STEM CELLS

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents Washington, D.C. 20231

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with 37 C.F.R. §§ 1.97 et. seq., the enclosed materials are brought to the attention of the Examiner for consideration in connection with the above-identified patent application. Applicants respectfully request that this Information Disclosure Statement be entered and the documents listed on the attached Form 1449 be considered by the Examiner and made of record. Pursuant to the provisions of MPEP 609, Applicants request that a copy of the 1449 form, initialed as being considered by the Examiner, be returned to the Applicants with the next official communication.

Pursuant to 37 C.F.R. §1.97(b), it is believed that no fee or statement is required with the Information Disclosure Statement. However, if fees are deemed to be due, they may be charged to Deposit Account No. 19-0743 in order to have this Information Disclosure Statement considered.

The Examiner is invited to contact the Applicants' Representative at the below-listed telephone number if there are any questions regarding this communication.

Respectfully submitted,

JACKIE R. BICKENBACH ET AL. By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.

P.O. Box 2938

Minneapolis, MN 55402

612-373-695

Date 40017,2003

Reg. No. 39,665

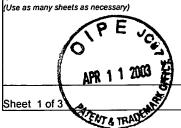
CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, Washington, D.C. 20231, on this 7th day of April, 2003 (mm 24)

andis B. Buending

Name

PTO/SB/08A(10-01)
Approved for use through 10/31/2002. OMB 651-0031
US Patent & Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT



Inder the Paperwork Reduction Act of 1995, no persons are	equired to respond to a collection of information unless it contains a valid OMB control number
Complete if Known	
Application Number	09/820198
Filing Date	March 28, 2001
First Named Inventor	Bickenbach, Jackie
Group Art Unit	1651
Examiner Name	Lankford, Jr., Leon
	7

Attorney Docket No: 875.029US1

US PATENT DOCUMENTS							
Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	Filing Date If Appropriate	
	US-5,686,307	11/11/1997	Wille, Jr., J. J.			07/11/1995	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	T ²
•	WO-99/47644	09/23/1999	Kaur, P., et al.			

	OTHER	R DOCUMENTS NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
		BICKENBACH, J. R., "A novel sorting method yields a pure population of viable	
		stem cells which reforms a complete epidermis with long-term recombinant gene	
		expression", Abstracts of the 60th Annual Meeting of The Society for	
		Investigative Dermatology, Chicago, May 5-9, 1999, Published in the Journal of	
		Investigative Dermatology, Vol. 112, No. 4 (April 1999), 2 pages	ļ
		BICKENBACH, J. R., "Identification and Behavior of Label-retaining Cells in Oral	1
		Mucosa and Skin", <u>J. Dent. Res., 122C,</u> (August 1981),1611-1620	
	_	BICKENBACH, J. R., et al., "Identification and Locatlization of Label-Retaining	
	,	Cells in Hamster Epithelia", J. Invest. Dermatol., 82:6, (June 1984),618-622	
	_	BICKENBACH, J. R., et al., "Label-Retaining Cells in Human Embryonic and	
		Fetal Epidermis", <u>J. Invest. Dermatol. 88,</u> (January 1987),42-46	
		BICKENBACH, J. R., et al., "Rate of loss of tritiated thymidine label in basal cells	
	•	in mouse epithelial tissues", Cell Tissue Kinet, 19, (May 1986),325-333	
		BICKENBACH, J. R., et al., "Selection and Extended Growth of Murine	
	`	Epidermal Stem Cells in Culture", Experimental Cell Research 244, (1998),184-	ŀ
		195	<u> </u>
		BICKENBACH, J. R., et al., "Transduction of a Preselected Population of Human	1
	•	Epidermal Stem Cells: Consequences for Gene Therapy", Proceedings of the	
		ASsociation of American Physicians, III:3, XP-002182787,(May/June 1999),184-	
		189	
		BLAU, H., et al., "Gene therapy: Progress, problems, prospects", Nature	
	•	Medicine, 3:6, (June 1997),612-613	
		CHUNG, S. Y., "Expression of the Human Keratin Gene (K1) in Transgenic Mice	
·	•	is Tissue- and Development-Specific but Altered with Respect to Differentiation	
		State", Molecular and Cellular Differentiation, 2(1), (1994),61-81	<u> </u>
	~	COMPTON, C. C., et al., "Skin Regenerated from Cultured Epithelial Autographs	
	,	on Full-Thickness Burn Wounds from 6 Days to 5 Years after Grafting",	İ
		Laboratory Investigation, 60(5), (May 1989),600-612	
		DELLAMBRA, E., et al., "Corrective Transduction of Human Epidermal Stem	
		Cells in Laminin-5-Dependent Junctional Epidermolysis Bullosa", Human Gene	
		<u>Therapy, 9,</u> (1998),1359-1370	

EXAMINER

DATE CONSIDERED

Substitute for form 1449A/PTO Complete if Known INFORMATION DISCLOSURE **Application Number** 09/820198 STATEMENT BY APPLICANT March 28, 2001 **Filing Date** Bickenbach, Jackie **First Named Inventor** 1651 **Group Art Unit** Lankford, Jr., Leon **Examiner Name** Attorney Docket No: 875.029US1

	OTHER	R DOCUMENTS NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	•	DENG, H., et al., "Sustainable cutaneous gene delivery", Nature Biotech, 15(13), (December 1997),1388-1391	
	`	FENJIVES, E. S., et al., "Loss of Expression of a Retrovirus-Transduced Gene in Human Keratinocytes", J. Invest. Dermatol., 106(3), (March 1996),576-578	
	`	FIBISON, W. J., "Gene Therapy", Nursing Clinics of North America, 35(3), (September 2000),757-772	
		FLOWERS, M. E., et al., "Long-term transplantation of canine keratinocytes made resistant to G418 through retrovirus-mediated gene transfer", <u>Proc. Natl. Ada. Sci. USA, 87(6)</u> , (March 1990),2349-2353	
	•	FUCHS, E., "Epidermal Differentiation: The Bare Essentials", J. Cell Biol., 111(6), (December 1990),2807-2814	
	14	GARLICK, J. A., et al., "Keratinocyte Gene Transfer and Gene Therapy", Crit Rev Oral Biol Med, 7(3), (1996),204-221	
	`	GARLICK, J. A., et al., "Retrovirus-Mediated Transduction of Cultured Epidermal Keratinocytes", J. Investe. Dermatol., 97(5), (November 1991),824-829	
		GHAZIZADEH, S., et al., "In vivo transduction of mouse epidermis with recombinant retroviral vectors: implications for cutaneous gene therapy", Gene Therapy, 6(7), (July 1999),1267-1275	
	`	GOODELL, M. A., et al., "Isolation and Functional Properties of Murine Hematopoietic Stem Cells that are Replicationg in Vivo", <u>J. Exp. Med., 183(4)</u> , (April 1996),1797-1806	
	•	GREENHALGH, D., et al., "Epidermis: An Attractive Target Tissue for Gene Therapy", J. Invest. Dermat., 103(5), (November 1994),63S-69S	
	`	JACKSON, K. A., et al., "Hematopoietic potential of stem cells isolated from murine skeletal muscle", <u>Proc. Natl. Acad. Sci., 96(25)</u> , (December 1999),14482-14486	
	`	KHAVARI, P. A., "Therapeutic gene delivery to the skin", Molecular Medicine Today, 3, (1997),533-538	
		KORGE, B. P., et al., "The molecular basis for inherited bullous diseases", <u>J.</u> Biol. Med., 74(2), (February 1996),59-70	
	`	MACKENZIE, I., et al., "Influence of Connective Tissues on the In Vitro Growth and Differentiation of Murine Epidermis", Epith. Cell Biol., 2(3), (1993),107-119	
	•	MACKENZIE, I., "Retroviral Transduction of Murine Epiermal Stem Cells Demonstrates Clonal Units of Epidermal Structure", <u>J. Invest. Dermatol.</u> , 109(3), (September 1997),377-383	
		MORGAN, J. R., et al., "Expression of an Exogenous Growth Hormone Gene by Transplantable Human Epidermal Cells", <u>Science</u> , 237, (September 1987),1476-1479	
	`	MORRIS, R. J., et al., "Highly Persistent Label-Retaining Cells in the Hair Follicles of Mice and Their Fate Following Induction of Anagen", <u>J. Invest.</u> <u>Dermatol.</u> , 112(4), (April 1999),470-475	

EXAMINER

Sheet 2 of 3

DATE CONSIDERED

PTO/SB/084(10-01
Approved for use through 10/31/2002, ONE 651-003
US Patient & Trademark Office: U.S. DEPARTMENT OF COUNCERCY.
The Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMS control number Substitute for form 1449A/PTO Complete if Known INFORMATION DISCLOSURE **Application Number** 09/820198 STATEMENT BY APPLICANT March 28, 2001 Filing Date Bickenbach, Jackie **First Named Inventor Group Art Unit** 1651 APR 1 1 2003 **Examiner Name** Lankford, Jr., Leon

Attorney Docket No: 875.029US1

	OTHE	R DOCUMENTS NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	,	MOUNTAIN, A., "Gene therapy: the first decade", <u>Trends in Biotechnology</u> , 18(3), (March 2000),119-128	
	`	OTTO, W. R., et al., "Survival of Allogeneic Cells in Cultured Organotypic Skin Grafts", Plast. Reconstr. Surg., 96(1), (July 1995),166-176	
	\	REDDI, A. H., "Morphogenesis and tissue engineering of bone and cartilage: inductive signals, stem cells, and biomimetic biomaterials", <u>Tissue Engineering</u> , 6(4), (2000),351-359	
	•	RHEINWALD, J. G., et al., "Serial cultivation of strains of human epidermal keratinocytes: the formation of keratinizing colonies of single cells", <u>Cell, 6(3)</u> , (November 1975),331-344	
	`	ROTHNAGEL, J. A., et al., "Analysis, diagnosis, and molecular genetics of keratin disorders", Current Opinion in Dermatology, (1995),211-218	
	`	SANES, J. R., "Analysing cell lineage with a recombinant retrovirus", <u>Trends in Neurosciences</u> , 12(1), (1989),21-28	
	`	STENN, K. S., et al., "Dispase, a neutral protease from Bacillus Polymyxa, is a powerful fibronectinase and Type IV collagenase", <u>J. Inveset. Dermat.,93(2)</u> , (August 1989),287-290	
	`	VOGEL, J. C., "Keratinocyte Gene Therapy", Arch. Dermat., 129, (November 1993),1478-1483	
	`	VOGT, P. M., et al., "Genetically modified keratinocytes transplanted to wounds reconstitute the epiermis", <u>Proc. Natl. Acad. Sci., 91(20),</u> (September 1994),9307-9311	
	•	WALTHER, W., et al., "Therapeutic genes for cancer gene therapy", Molecular Biology, 13(1), (November 1999),21-28	
	\	WANG, F., et al., "Gene therapy and metabolic engineering", Metabolic Engineering, 2, (2000),126-139	

EXAMINER

Sheet 3 of 3

DATE CONSIDERED